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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,031	12/01/2003	Oleg Shikhman	INE-0061D3	4709
23413	7590	05/25/2007		
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			EXAMINER SONNETT, KATHLEEN C	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 05/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/726,031

Applicant(s)

SHIKHMAN ET AL.

Examiner

Kathleen Sonnett

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments, filed 3/13/2007, with respect to the rejection(s) of claim(s) 1 and 5 under 35 U.S.C. 102(b) as anticipated by Habermeyer et al. (U.S. 5,575,801) and claims 2-4, 6, 7, 9-15, 18-23, and 25 under 35 U.S.C. 103(a) with Habermeyer et al. as the base reference combined with various teaching references as presented in the office action dated 9/13/2006 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references as stated below in the art rejections.

### *Double Patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. **Claims 1-20 and 25** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 35-54 and 64, respectively, of copending Application No. 10/037,899 (as filed on 4/25/2007). Claims 35-54 have been withdrawn but not canceled. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting

rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims 21-24** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-63 of copending Application No.

10/037,899 in view of Iglesias (U.S. 4,134,406). Claims 60-63, as filed 4/25/2007, have been withdrawn but not canceled. Claims 60-63 of copending Application No. 10/037,899 claim the invention substantially including mounting a suture loading assembly upon a tubular portion of a suture securing instrument but fail to claim that the suture loading assembly has a body and that it is mounted onto the suturing instrument with an attaching member the extends from the body of the suture threading assembly. However, Iglesias discloses that it is old and well known to those skilled in the art to mount a first medical instrument onto a second medical instrument by using an attaching member that extends down from a body portion of the first medical instrument (see fig. 1). Such attaching member provides a quick and easy way to attach two instruments while still allowing relative movement between the two when positioning of the instruments is required. Therefore, it would have been obvious to one of ordinary skill in the art to modify claims 60-63 of copending Application No. 10/037,899 to include the limitation of an attaching member the extends from the body of the suture threading assembly to mount the assembly to the body of the suture securing instrument as made obvious by Iglesias in order to

provide a quick and easy means of mounting the suture loading assembly upon the suture securing instrument.

This is a provisional obviousness-type double patenting rejection.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 2, and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (U.S. 4,779,616). Johnson discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (10), an attaching member (12) extending from the body and a flexible loop (14) extending from a distal end of the body. Regarding the attaching member, the language “for attaching the body to the surgical instrument” is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. Depending on the structure of the surgical instrument, the member can be attached by a clip member that extends from the surgical instrument and engages the attaching member (12). The body includes a bore from which the wire loop extends.

6. **Claims 1-5 and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Grossi et al. (U.S. 4,917,082). Grossi et al. discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (62), an attaching member (68,70) extending from the body and a flexible loop (22) extending from a distal end of the body (see fig. 1-4). Regarding the attaching member, the language “for

attaching the body to the surgical instrument” is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. The body includes a bore from which the wire loop extends (col. 4 ll. 58-62).

7. Regarding claims 3 and 4, the attaching member includes two legs extending from the body, an inner portion of each leg curved to accept a cylindrical member of a surgical instrument wherein the attaching member is slidable along the cylindrical member of the surgical instrument (see fig. 1 and 3). The outer portion of each leg includes an indented area where it joins to body (62). This can be used as a finger grip if one where to grab the device at this point.

8. Regarding claim 5, the body is now being considered element (60) and the cap is being considered portion (62), which surrounds element (60). The attaching member is still (68,70) which extends from body (60) since body (60) is within cap (62).

9. **Claims 1, 2, and 5-9** are rejected under 35 U.S.C. 102(b) as being anticipated by Riza (U.S. 5,501,692). Riza discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (30), an attaching member (20) extending from the body and a flexible loop (36) extending from a distal end of the body. Regarding the attaching member, the language “for attaching the body to the surgical instrument” is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. Depending on the structure of the surgical instrument, the member can be attached by a clip member that extends from the surgical instrument and engages the attaching member (20) at its proximal-most end (21). The body includes a bore from which the wire loop extends.

10. Regarding claims 5-7, the device includes a cap (11) surrounding a portion of the body (see fig. 4). The cap includes indents in the sides of the cap that serve as finger grips. Portions

(12) and (13) are being considered the base line and the remaining portions of cap (11) are indented from this base line. These can serve as finger grips.

11. Regarding claim 8, the cap includes openings for receiving the body and the attaching member (see fig. 4).

12. **Claims 11 and 13-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Iglesias (U.S. 4,134,406). Iglesias discloses a suture securing instrument comprising an elongated tubular portion having a distal and proximal end, the distal end including a ferrule accepting opening (distal end of tube 10), the proximal end attached to a handle assembly (any of the structure at proximal-most end such as 32) and a suture loading assembly in combination with the instrument comprising a body (22), an attaching member (40) extending from the body for attaching the body to the elongated tubular portion of the suture securing instrument and a flexible loop (28) extending from a distal end of the body. The instrument (8 surrounded by 10) is being considered a suture securing instrument since it meets the limitations of the claim: it comprises an elongated tubular portion having distal and proximal ends and a distal end including an opening which is capable of accepting a ferrule and a proximal end attached to a handle assembly.

13. Regarding claims 13-15, the attaching member is slidable along the tubular portion of the suturing securing instrument (col. 3 ll. 10-14). The attaching member includes two legs extending from the body, an inner portion of each leg curved to accept the tubular portion of the suture-securing instrument. As seen in fig. 2, the legs have an indented area near their base (where 22 slides into the attaching member) and this can be used as a finger grip.

14. **Claims 11, 12, and 20** are rejected under 35 U.S.C. 102(b) as being anticipated by Ek (U.S. 5,935,149). Ek discloses a suture securing instrument comprising an elongated tubular portion having a distal and proximal end, the distal end including a ferrule (212) accepting

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opening (see fig. 10) the proximal end attached to a handle assembly (see fig. 12) and a suture loading assembly in combination with the instrument comprising a body (400), an attaching member (402) extending from the body for attaching the body to the elongated tubular portion of the suture securing instrument (col. 5, ll. 63-67) and a flexible loop (410) extending from a distal end of the body. The loop is threaded through the ferrule accepting opening (see fig. 10) and loop (410) is made of wire bent into a diamond shape.

15. **Claims 11, 18, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (U.S. 5,520,702). Sauer et al. discloses a suture securing instrument comprising an elongated tubular portion having a distal and proximal end, the distal end including a ferrule accepting opening (62), the proximal end attached to a handle assembly and a suture loading assembly (304) in combination with the instrument, the suture loading assembly comprising a body (straight portion extending from loop 304), an attaching member (rounded proximal portion) extending from the body for attaching the body to the elongated tubular portion of the suture securing instrument, and a flexible loop extending from a distal end of the body. If the device were held such that the attaching member is above the suture securing instrument, the attaching member is larger than aperture (62) and will just sit on top of the elongated tubular portion. As mentioned above, the language "for attaching the body to the surgical instrument" is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. A third piece that clips onto both the elongated tubular member and the attaching member could be used to mount the attaching member to the elongated tubular member.

16. Regarding claim 18, the suture-securing instrument comprises an aperture in the elongated tubular portion, the aperture located proximally of the ferrule-accepting opening, the flexible loop threaded through the aperture prior to threading through the ferrule-accepting



opening. The ferrule is placed at an angle as seen in Fig. 3 and therefore, aperture (76) is proximal to the ferrule opening.

17. Regarding 19, a ferrule is positioned in the ferrule accepting opening.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson.

Johnson discloses the invention substantially as stated above but does not expressly disclose a plug used to retain the wire within the body but instead discloses swaging the wire within the body to hold the wire in place (see col. 2 lines 23-26). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a plug to retain the wire within the body because Applicant has not disclosed that the use of such a plug provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the modified device of Johnson and applicant's invention to perform equally well with either the claimed plug or the swaging taught by Johnson because both perform the same function of connecting the wire loop to the body. Therefore, it would have been prima facie obvious to further modify Johnson to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of modified Johnson.

20. **Claims 21-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (U.S. 5,520,702) in view of Sauer (U.S. 5,643,289) and Iglesias (U.S. 4,134,406). Sauer et al. ('702) discloses the method of threading a suture securing instrument comprising threading a flexible loop extending from the suture loading assembly through a ferrule within a distal end of the suture loading assembly, inserting suture material through the flexible loop (304) and pulling the flexible loop proximally until the suture material is threaded through the ferrule (see fig. 4 and 5). The suture loading assembly has a body as seen in fig. 4 but does not include an attaching member that extends from the body to mount the assembly to the body of the suturing device. Sauer et al. fails to disclose mounting a suture loading assembly upon a tubular portion of the suture-securing instrument and sliding the suture loading assembly proximally along the tubular portion of the securing instrument.

21. However, Sauer et al. ('289) discloses that threading tools can be modified so that the threading can be accomplished intracorporeally (see col. 7, ll. 17-21). Iglesias discloses that it is old and well known to mount one medical device to another when the devices are used in conjunction with one another. In particular, Iglesias discloses mounting a wire loop (28) onto another medical device (10), with which it is used in conjunction. In the device of Iglesias, there is an attaching member (40) that extends from the body (22) of the device. Such an arrangement allows the loop to be inserted and removed easily in a very small space (intracorporeally). This is advantageous in endoscopic procedures since space at the surgical site is generally limited. Sauer et al. ('702) discloses the use of a suture loading assembly comprising a loop to pull suture proximally along the tubular portion of the suture-securing instrument (see fig. 4, 5, and 7) and Sauer ('289) teaches that the threading tool can be modified so that the threading can be accomplished intracorporeally. Using the teachings of Iglesias, it would be obvious to one of ordinary skill in the art to modify the method of Sauer et al. to

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include mounting the suture loading assembly onto the tubular portion of the suture securing instrument through an attaching member that extends from the body of the suture threading assembly in order to modify the threading assembly as suggested by Sauer ('289) to gain the advantage of providing a threading assembly that can thread intracorporeally.

22. Regarding claim 25, Sauer ('702) discloses a kit for securing suture material within a body of a patient, the kit comprising a cutting and crimping device, a ferrule loaded into the cutting and crimping device, and a suture loading assembly, a flexible loop extending from the suture loading assembly threaded through the ferrule. Sauer fails to disclose a suture loading assembly that is mounted onto a tubular portion of the cutting and crimping device.

23. However Sauer et al. ('289) discloses that threading tools can be modified so that the threading can be accomplished intracorporeally (see col. 7, ll. 17-21). Sauer ('289) is silent as to how this is accomplished. Iglesias discloses that it is old and well known to mount one medical device to another when the devices are used in conjunction with one another. In particular, Iglesias discloses mounting a wire loop (28) onto another medical device (10), with which it is used in conjunction. In the device of Iglesias, there is an attaching member (40) that extends from the body (22) of the device. Such an arrangement allows the loop to be inserted and removed easily in a very small space (intracorporeally). This is advantageous in endoscopic procedures since space at the surgical site is generally limited. Using the teachings of Iglesias, it would be obvious to one of ordinary skill in the art to modify the device of Sauer et al. to include mounting the suture loading assembly onto the tubular portion of the suture securing instrument through an attaching member that extends from the body of the suture threading assembly in order to modify the threading assembly as suggested by Sauer ('289) to gain the advantage of providing a threading assembly that can thread intracorporeally.

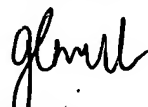
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 5/14/2007

  
**GLENN K. DAVIS**  
**PRIMARY EXAMINER**